K061750

AUG 11 2006

510(k) Summary for the
Dimension Vista™ System Lipid Calibrator
(LIPID CAL – KC220)

A. 510(k) Number:

B. Analytes: High density lipoprotein cholesterol (HDLC) and low density cholesterol lipoprotein (LDLC).

C. Type of Test: Calibrator Material

D. Applicant: Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

E. Proprietary and Established Names:

Dimension Vista™ System Lipid Calibrator
(LIPID CAL – KC220)

F. Regulatory Information:

1. Regulation section: 21 CFR § 862-1150 – Calibrator
2. Classification: Class II
3. Product Code: JIX – Calibrator, Multi-Analyte Mixture
4. Panel: Clinical Chemistry

G. Intended Use: The LIPID CAL is an *in vitro* diagnostic product for the calibration of high density lipoprotein cholesterol (HDLC) and low density lipoprotein cholesterol (LDLC) methods on the Dimension Vista™ System.

H. Device Description:

LIPID CAL is a liquid, multi-analyte, human albumin based product containing human lipoproteins and bovine gamma globulins. The kit consists of six vials, three vials of Calibrator A, and three vials of Calibrator B which are ready for use (no preparation is required). The volume per vial is 1.5 mL.

I. Substantial Equivalence Information:

	Device	Predicates	
Item	**Dimension Vista™ System Lipid Calibrator**	**Dimension® HDL Calibrator K983850**	**Dimension® ALDL Calibrator K020723**
Intended Use	The LIPID CAL is an *in vitro* diagnostic product for the calibration of high density lipoprotein cholesterol (HDLC) and low density lipoprotein cholesterol (LDLC) methods on the Dimension Vista™ System.	The HDL Cholesterol Calibrator is an in vitro diagnostic product to be used to calibrate the Dimension® clinical chemistry system for the HDL Cholesterol (HDL) method.	The ALDL Calibrator is an in vitro diagnostic product intended to be used to calibrate the automated LDL (ALDL) method for the Dimension® clinical chemistry system.
Analytes	High density lipoprotein cholesterol and low density lipoprotein cholesterol.	High density lipoprotein cholesterol.	Low density lipoprotein cholesterol.
Form	Liquid.	Liquid.	Lyophilized.
Traceability	National Cholesterol Education Program (NCEP) reference method.	NBS SRM 911 a.	NCEP beta-quantification reference method for LDL-C b.
Matrix	Human albumin based product containing human lipoproteins and bovine gamma globulins.	Stabilized aqueous solution containing cholesterol.	Lyophilized buffered bovine serum albumin-based product supplemented with human low density lipoprotein cholesterol.
Number of Levels	Two levels.	Three levels.	Three levels.

a - NBS-SRM: National Bereau of Standards - Standard Reference Material.
b – NCEP - National Cholesterol Education Program

J. Standard/Guidance Document Referenced:

1. Guidance: Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final, 02/22/1999
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use, 11/30/2004

2. Standards: CEN 13640 Stability testing of In-Vitro Diagnostic Devices
ISO 14971:2000 Medical devices -Application of risk management to medical devices

K. Performance Characteristics:

1. Stability: Target shelf life for the Dimension Vista™ Lipid Calibrator is 12 months. Calibrator shelf life is determined by comparing results of the product stored at 4°C with control stored at -20°C. The method is calibrated from this stored material. The 4°C material values are recovered versus the calibration. Recovery versus time is monitored and percent change over time is determined. Percent change should be less than or equal to 3%. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc.
A vial punctured by the instrument and stored on board has a seven day claim.
An open vial not stored on board of instrument, but recapped and stored in a refrigerator has a stability claim of 30 days.

   For testing, vials are opened /punctured on day zero. A quantity sufficient for multiple calibrations is removed and the vials are recapped and stored at 2 – 8 °C. Opened/punctured vials are tested on days 8, 15, 22, and 32 versus freshly opened vials.

2. Traceability: The assigned values of the Dimension Vista™ Lipid Calibrator are standardized to the enclosed table of assigned values:

Constituent	Traceability
HDLC	National Cholesterol Education Program (NCEP) reference method
LDLC	National Cholesterol Education Program (NCEP) reference method

3. Bottle Value Assignment:

Human HDL (bovine based) and LDL (human serum based) are weighed protein containing solutions. The HDL Master Pool and the LDL Anchor Pool are stored at -70 °C.
HDL human serum samples with Abel-Kendall values are used to produce a standard curve for the assignment of the Master Pool.
LDL human serum pools with values from reference laboratories (CRMNL) are used to produce a standard curve for assignment of the Anchor Pool.
The commercial lot is made by adding human HDL and LDL to base matrix in appropriate concentrations for upper calibrator levels. The concentration of each level is verified by using an instrument calibrated with the Master Pool / Anchor Pools.
The final bottle values for each level of the commercial lot is assigned and verified using multiple instruments by testing N = 90 replicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Victor M. Carrio
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Newark, DE 19714-6101

AUG 1 1 2006

Re: k061750
Trade/Device Name: Dimension Vista™ Lipid Calibrator (KC220)
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: June 30, 2006
Received: June 21, 2006

Dear Mr. Carrio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K061750

Device Name:

Dimension Vista™ Lipid Calibrator (KC220)

Indications for Use:

The LIPID CAL is an in vitro diagnostic product for the calibration of high density lipoprotein cholesterol (HDLC) and low density lipoprotein cholesterol (LDLC) methods on the Dimension Vista™ System.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

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